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No. 02-869

IN THE
Supreme Court of the United States

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,
Petitioner,
v.
RHONDA M. MEDOWS, Secretary, Agency for Health Care Administration of the State of Florida; and BOB SHARPE, Deputy Secretary of Medicaid, Agency for Health Care Administration of the State of Florida,
Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

BRIEF OF WASHINGTON LEGAL FOUNDATION, KIDNEY CANCER ASSOCIATION, 60 PLUS ASSOCIATION, AND ALLIED EDUCATIONAL FOUNDATION AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

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QUESTION PRESENTED

Whether the federal Medicaid statute, 42 U.S.C. § 1396r-8, allows a State to impose broad restrictions on Medicaid patients' access to prescription drugs if manufacturers refuse to provide greater rebates than the rebates specified in the federal statute.

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BRIEF OF WASHINGTON LEGAL FOUNDATION, KIDNEY CANCER ASSOCIATION, 60 PLUS ASSOCIATION, AND ALLIED EDUCATIONAL FOUNDATION AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

INTERESTS OF *AMICI CURIAE*

The Washington Legal Foundation (WLF) is a non-profit public interest law and policy center with supporters in all 50 states, including many in Florida.[1] WLF devotes a substantial portion of its resources to defending and promoting free enterprise, individual rights, and a limited and accountable government. In particular, WLF has appeared before this and other federal courts to oppose government efforts to restrict consumer access to prescription drugs. *See, e.g., Pharmaceutical Research and Manufacturers of America v. Concannon,* No. 01-188 (U.S., decision pending). WLF recently successfully challenged the constitutionality of Food and Drug Administration restrictions on commercial speech by pharmaceutical manufacturers. *Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998), *appeal dism'd,* 202 F.3d 331 (D.C. Cir. 2000).

The Kidney Cancer Association is a patient and survivor-led voluntary health agency pursuing the goal of a world without kidney cancer through research, education, and advocacy.

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[1] Pursuant to Supreme Court Rule 37.6, *amici curiae* state that no counsel for a party authored this brief in whole or in part; and that no person or entity, other than *amici* and their counsel, contributed monetarily to the preparation and submission of this brief.

The 60 Plus Association is a Virginia-based seniors' advocacy group devoted to the free market, free enterprise system. 60 Plus is opposed to price controls on prescription drugs because: (1) they stifle pharmaceutical research leading to the medical miracles enabling seniors to live longer and better and stay out of hospitals; and (2) they result in shortages, as evidenced by the shortcomings of the Canadian health care system.

The Allied Educational Foundation (AEF) is a non-profit charitable and educational foundation based in Englewood, New Jersey. Founded in 1964, AEF is dedicated to promoting education in diverse areas of study, such as law and public policy, and has appeared as *amicus curiae* in this Court on a number of occasions.

Amici are concerned that the Florida program will have long-term adverse effects on health care in this country. The program threatens to interfere with Medicaid recipients' access to the best-available pharmaceuticals. Moreover, by interfering with the free market in pharmaceutical sales, the program threatens to discourage research and development of new, life-saving drugs and to Balkanize what is now an efficient and uniform Medicaid rebate program.

Amici have no direct financial interest in the outcome of this case. They are filing due solely to their interest in improved health care for all Americans. *Amici* are filing this brief with the consent of all parties. The written consents have been lodged with the Clerk of the Court.

STATEMENT OF THE CASE

In the interests of brevity, WLF hereby adopts by reference the Statement of the Case contained in the Petition.

In brief, Florida has adopted a law that restricts Medicaid patients' access to prescription drugs. The law is designed as a price-control measure; Florida imposes access restrictions only on those drugs whose manufacturers are unwilling to provide a rebate of at least 25% on the cost of the drugs. The law has been in effect since July 1, 2001 and apparently is working as planned: sales have dropped sharply for those drugs subject to the access restrictions and have increased significantly for many of the drugs not subject to the restrictions.

It is uncontested that the Florida law imposes access restrictions based solely on sales price. Access restrictions are imposed on *all* products whose manufacturers are unwilling to offer a 25% rebate, without regard to the effectiveness of those drugs and without regard to the availability of other drugs that provide equivalent benefits.

Petitioner Pharmaceutical Research and Manufacturers of America ("PhRMA") filed suit against the Florida access restriction law, claiming that the restrictions are illegal because they conflict with provisions of the federal Medicaid law. PhRMA contends that the access restrictions adopted by Florida constitute the use of a Medicaid drug "formulary" within the meaning of § 1927(d)(4) of the Social Security Act ("SSA"), 42 U.S.C. § 1396r-8(d)(4), but that Florida has not complied with the prerequisites for the use of such a formulary. Florida responds that its program does not constitute a "formulary" within the meaning of federal law,

but rather is a "prior authorization program" permitted under SSA § 1927(d)(5).

PhRMA filed suit against the Florida program on August 7, 2001 in U.S. District Court for the Northern District of Florida, Tallahassee Division, alleging that the Florida program conflicted with SSA § 1927(d)(4) and therefore was invalid under the Supremacy Clause (Article VI, Clause 2) of the Constitution; PhRMA sought an injunction against continuation of the program. On September 20, 2001, the magistrate judge to whom the matter had been referred recommended that PhRMA's motion for a preliminary injunction be denied. Petition Appendix ("Pet.") App.41 - App.59. The magistrate judge agreed with Florida that its program was a "prior authorization program" permitted under SSA § 1927(d)(5). He found that Florida's program served "the goals of the Medicaid program, to provide drugs to Medicaid beneficiaries at the lowest cost possible." *Id.* at App.57. He concluded:

> Nor has Plaintiff pointed to any portion of the federal law which forbids a State from seeking additional rebates from drug manufacturers. In the absence of a specific federal statutory provision, a State should be free, as the buyer in the market place, to try to obtain the best price it can.

Id. at App.58.

On December 28, 2001, the district court in a brief order adopted the magistrate's report, denied PhRMA's motion for a preliminary injunction and its cross-motion for summary judgment, and granted defendants' motion to

dismiss or, in the alternative, for summary judgment. *Id.* at App.39 - App.41.

On September 6, 2002, the U.S. Court of Appeals for the Eleventh Circuit affirmed. *Id.* at App.1 - App.39. The appeals court agreed with PhRMA that the Florida program would be invalid under federal law if it were, in fact, a "formulary" within the meaning of SSA § 1927(d)(4). *Id.* at App.19. But the appeals court agreed with the lower courts that the Florida program created not a "formulary" but a "prior authorization program" within the meaning of SSA § 1927(d)(5). *Id.* The court concluded that the essential ingredient of any Medicaid "formulary" is a reservation by the State of the authority to deny coverage for a drug not included in the formulary *regardless* how insistent the patient's physician may be that the patient's survival depends on access to the drug. *Id.* at App.21 - App.22. The court said that the Florida program *required* the State to acquiesce in the medical judgment of an insistent treating physician who has jumped through all the necessary hoops, and thus that the program does not fit the definition of a "formulary." *Id.*

Relying heavily on the decision of the U.S. Court of Appeals for the First Circuit in *Pharmaceutical Research and Manufacturers of America v. Concannon,* 249 F.3d 66 (1st Cir. 2001), *cert. granted,* 122 S. Ct. 2657 (2002), the appeals court determined that the Florida program directly served the "primary" purpose of Medicaid of enabling "states to provide medical services to those whose income and resources are insufficient to meet the costs of necessary medical services." *Id.* at App.23 (quoting *Concannon,* 249 F.3d at 75). The court concluded that the Florida program would drive down Florida's costs in providing drugs to Medicaid recipients, thereby granting Florida "the potential

for providing more and better medical services to the target population." *Id.*

The appeals court declined to consider the legislative history submitted by PhRMA in support of its view regarding the meaning of a Medicaid "formulary." The court said that, in its view, SSA §§ 1927(d)(4) and (d)(5) were unambiguous and thus that "recourse to legislative history is unnecessary." *Id.* at App. 26.

REASONS FOR GRANTING THE PETITION

This case raises health care issues of exceptional importance. Florida insists (and the appeals court agreed) that it is entitled, in an effort to reduce expenditures, to restrict significantly Medicaid patient access to drugs that are routinely available to Medicaid patients in other States. The program has worked precisely as planned -- whenever Florida has restricted access to a drug, Medicaid prescriptions for those drugs have dropped precipitously. Manufacturers who wish to avoid those restrictions on their products have acceded to Florida's demand that they pay the State a 25% rebate on all drug sales.

The cost-saving advantages derived by Florida from its program are obvious. *Amici* submit that the harm inflicted by the program on Medicaid recipients in Florida is equally obvious. Their access to essential pharmaceutical products is reduced, and they receive nothing in return: all benefits accrue to the State government. The Court should grant review to determine whether Congress intended to permit States to leverage their delegated Medicaid powers in this manner.

Although it raises issues distinct from those raised in *Concannon,* this case raises precisely the same types of health care concerns. In *Concannon*, Maine is attempting to leverage its Medicaid powers by threatening to restrict the access of Medicaid patients to the drugs of manufacturers who refuse to provide discounts to Medicaid-ineligible lower- and middle-income residents. In this case, Florida is acting out of somewhat less altruistic motives: it is threatening the same actions as a means of lowering its own costs. Under both the Maine and Florida programs, the health of Medicaid recipients is being placed at risk by their reduced access to life-saving drugs that are being withheld based solely on cost considerations. The Court deemed the federal statutory questions at issue in *Concannon* sufficiently weighty to warrant a grant of review in that case; similar considerations warrant the Court's review of the important federal statutory questions raised herein.

I. REVIEW IS WARRANTED IN LIGHT OF THE MAJOR IMPORTANCE OF THE QUESTION PRESENTED TO THE DELIVERY OF HEALTH CARE IN THIS COUNTRY

Rising use of prescription drugs by consumers has led in recent years to a significant increase in total expenditures for prescription drugs in this country. That increase in turn has led to efforts in numerous States to control prescription drug prices.

According to the National Conference of State Legislatures (NCSL), 2002 marked "the third consecutive year of intense state activity on prescription drug access, costs and pricing," and 30 States have now adopted some type of program designed to control drug prices. *See* NCSL,

2002 Prescription Drug Discount, Bulk Purchasing, and Price-Related Legislation, at www.ncsl.org/programs/health/drugdisc02.htm (updated December 11, 2002). New legislation mandating discount programs, bulk purchasing programs, expanded manufacturer rebates, and/or price controls are being considered in more than 39 States. *Id.* The pace at which such legislation is being considered has quickened following the First Circuit's 2001 decision in *Concannon*. The Center for Policy Alternatives ("CPA") reports that following that decision, 14 States (including Florida) have adopted programs intended to force manufacturers to lower their prescription drug prices. CPA, *Summary of Legislative Activity on Prescription Drug Prices* (June 20, 2002 Update) *at* www.stateaction.org/issues/healthcare/prescription/2002.pdf (visited January 6, 2003). A number of those programs are virtually indistinguishable from Florida's supplemental Medicaid rebate program. Michigan's virtually identical program, approved in January 2002, is being challenged by a coalition of manufacturer and patient groups in federal court in the District of Columbia. *PhRMA v. Thompson,* No. 02-CV-1306 (D.D.C., filed June 28, 2002).

In light of the large number of state statutes being adopted in this area, the need for the Court's guidance regarding the constitutionality of such legislation is readily apparent. Moreover, the need for guidance is significantly greater here than in *Concannon*, given that the Maine program at issue in *Concannon* is at present the only one of its kind, while the Florida program at issue here has been emulated by several other States.

The Florida program's potential for adverse impact on the health care of Medicaid recipients is also readily

apparent. Indeed, the very purpose of the program is to prevent those recipients from receiving prescriptions for drugs that the State has deemed too expensive -- a determination made by Florida without *any* effort to determine the drugs' cost-effectiveness. All the evidence submitted to the district court indicates that the program is working precisely as planned: drugs that Florida has subjected to a prior authorization requirement (because the manufacturer declined to grant a supplemental discount) are being prescribed far less often to Medicaid recipients.

The Eleventh Circuit speculated that Medicaid patients might not suffer adverse health effects when access is restricted to their (and their doctors') drugs of choice because, "Presumably, some doctors will learn to avoid the prior authorization program by routinely looking for a suitable drug on the preferred drug list." Pet. App.21 n.9. The evidence suggests otherwise. One recent study of a separate Florida program -- which, like the program at issue here, requires prior authorization of certain prescriptions -- concluded that in over 25% of the cases in which the prior authorization requirement prevented a prescription from being filled, the Medicaid patient ended up receiving no drug at all. Mary Kay Owens, *et al.*, Florida Center for Medicaid Issues, *Florida Medicaid Prescribed Drug Program: Four Brand Prescription Drug Limit Policy: Final Report--Phase I, June 2001* 4-5 (2001), available at www.vtmd.org/policy/team/T3-1-02-a.doc (visited January 6, 2003).

The Eleventh Circuit also speculated that the Florida program might enhance health care for Medicaid recipients because, "By stretching its Medicaid dollars, the Florida law has the potential for providing more and better medical services to the target population." Pet. App.23. But while

the appeals court may have divined such a "potential," that has never been Florida's stated purpose. Rather, Florida asserted repeatedly in the lower courts that it adopted the supplemental rebate program in order to *reduce* its overall Medicaid expenditures, not to use savings on prescription drug costs to enhance other services to Medicaid recipients. *See, e.g.*, Respondents' Eleventh Circuit Brief at 18.

In any event, efforts by other States to reduce overall Medicaid costs by restricting access to drugs have often proven to be unavailing, even as those efforts reduced the overall quality of health care. Patients who are denied (for cost reasons) the most effective prescription drugs often end up with otherwise-avoidable hospital stays. For example, a recent study in the New England Journal of Medicine described the negative impacts of a New Hampshire Medicaid provision that limited some program participants to three prescriptions per month. Although the policy reduced drug costs by 35%, nursing home admissions rose by 60%, and system-wide medical costs rose as well. The experience with program participants suffering from schizophrenia was particularly revealing. Caps on newer drugs saved $57 per patient annually but led to $1,530 in additional per-patient costs for visits to clinics and emergency rooms. S. Souneri, *et al.*, "Effects of Medicaid Drug Limits on Admissions to Hospitals," *New England Journal of Medicine,* 325 (1991) at 1072-77.

Canada imposes strict limits on government-funded access to prescription drugs. A recent survey of British Columbia doctors found that 27% of them had been forced to admit patients to hospitals as a result of government-mandated substitutions of prescription drugs. William

McArthur, "Canadian Medicine Isn't Cheap or Effective," *The Wall Street Journal*, Jan. 21, 2000, at A19.

Similarly, a recent study conducted by Columbia University economist Frank Lichtenberg attests to the cost savings that result from increased use of prescription drugs, because use of new (and often more expensive) medicines tends to lower all types of non-drug medical spending. Lichtenberg found that an $18 increase in spending on new prescription drugs reduces non-drug spending by $71.09, resulting in a net savings of $53.09. Frank Lichtenberg, "Are the Benefits of Newer Drugs Worth Their Costs? Evidence from the 1996 MEPS," 20 *Health Affairs* No. 5 (September/October 2001).

In light of that evidence, it is eminently reasonable to conclude that Congress would not have wanted States to restrict Medicaid recipients' access to prescription drugs in an effort to balance State budgets. In light of the importance of that question to the maintenance of quality health care among our nation's poorest citizens, this Court's review is warranted.

II. REVIEW IS WARRANTED BECAUSE THE APPEALS COURT HAS PLAINLY MISINTERPRETED SSA §§ 1927(d)(4) & (d)(5)

Review is warranted for the additional reason that the Eleventh Circuit has so plainly misinterpreted Congress's efforts to restrict the adoption of Medicaid "formularies." Congress intended to prevent precisely the type of restrictions on drug access -- restrictions based solely on cost, without regard to the drug's effectiveness -- that is at issue in this case.

Amici concur with PhRMA's analysis of SSA §§ 1927(d)(4) and 1927(d)(5) and will not repeat that analysis here. *Amici* nonetheless ask the Court to focus its attention on SSA § 1927(d)(4)(D). Under that provision, a State that excludes a drug from its "formulary" is *required* to create a "prior authorization program" under § 1927(d)(5) and to permit the excluded drug to be covered pursuant to the terms of that prior authorization program.[2] If Florida's interpretation of SSA § 1927 is accepted, then § 1927(d)(4)(D) makes absolutely no sense. A State wishing to set up a "formulary" under § 1927(d)(4) is required to meet numerous procedural requirements and to make numerous clinical findings before it is allowed to exclude a drug from its formulary -- and even then, as § 1927(d)(4)(D) makes clear, the State can impose no greater access restrictions on the excluded drugs than Florida has imposed under its alleged "prior authorization program." Why would a State ever jump through all those hoops if it could accomplish the same ends by simply renaming its

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[2] The principal purpose of a well-run formulary is to permit a payor to discourage use of drugs that do not provide any unique advantages to patients and may be more expensive, or at least less cost-effective, than other drugs whose use is encouraged. Thus, SSA § 1927(d)(4)(C) authorizes duly constituted formulary committees, after careful review, to determine that a specific drug "does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome . . . over other drugs included in the formulary" with respect to "the treatment of a specific disease or condition for an identified population." If such a determination is made, then the drug may be excluded from a State Medicaid formulary. But even when a State has acted properly in excluding a drug from its formulary, it still *must* (pursuant to § 1927(d)(4)(D)) permit coverage of the drug pursuant to a prior authorization program -- unless the drug is included within the very limited categories of drugs excluded from coverage under § 1927(d)(2).

"formulary" a "prior authorization program?" The answer, of course, is that it would never do so, with the result that the restrictions that Congress intended to impose on State programs would come to nothing.

The appeals courts' efforts to distinguish the Florida program from a § 1927(d)(4) "formulary" are unavailing and are based on a misinterpretation of the statute. The appeals court ruled that an essential ingredient of any Medicaid "formulary" is a reservation by the State of the authority to deny coverage for a drug not included in the formulary *regardless* how insistent the patient's physician may be that the patient's survival depends on access to the drug. Pet. App.21 - App.22.[3] The court concluded that the Florida program was not a "formulary" because (it concluded) Florida at the end of the day would always acquiesce in the medical judgment of an insistent treating physician who has sought prior authorization to prescribe to one of her Medicaid patients a drug on the prior authorization list. *Id.* But that interpretation is dependent on a statutory recognition of two separate types of "prior authorization programs": (1) a "prior authorization program" of the type Florida claims to have created pursuant to § 1927(d)(5); and (2) a "prior

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[3] While acknowledging that even a Medicaid formulary must, under § 1927(d)(4)(D), "permit coverage [of an excluded drug] . . . pursuant to a prior authorization program that is consistent with [§ 1927(d)(5)]," the appeal court "construe[d] this requirement to mean that a state must *consider* coverage for an excluded drug on a case-by-case basis." Pet. App.21 (emphasis in original). In other words, the appeals court viewed § 1927(d)(4)(D) as requiring a State that maintains a Medicaid formulary to *listen* to the entreaties of a doctor that his Medicaid patient should be given access to an excluded drug, but as granting the State absolute and final authority to overrule those entreaties.

authorization program" that must (per § 1927(d)(4)(D)) be maintained as an adjunct to any Medicaid formulary.

Section 1927(d) cannot plausibly be read as contemplating these two distinct types of prior authorization programs. Indeed, § 1927(d)(4)(D) explicitly states that the "prior authorization program" that is to be maintained as an adjunct to a Medicaid formulary must be "consistent with [§ 1927(d)(5)]," which sets forth "requirements of prior authorization programs." Florida claims that its program is a "prior authorization program" of the type contemplated by § 1927(d)(5). Thus, whatever statutory requirements apply to the Florida program also apply to the "prior authorization program" that any State adopting a Medicaid formulary would have to maintain. In sum, the appeals court has failed to explain how Florida's prior authorization program can be meaningfully distinguished from the prior authorization program that must be maintained in connection with a Medicaid formulary. In the absence of such a distinction, allowing Florida to impose prior authorization requirements on any or all drugs without regard to their cost effectiveness -- simply because it deems them too expensive -- would be to write out of the law Congress's carefully considered restrictions on State implementation of Medicaid formularies.

Finally, *amici* concur with PhRMA's assessment that the Court's disposition of *Concannon* could well call into question the Eleventh Circuit's analysis. *Amici* note that both cases are dependent (at least in part) on the meaning of SSA § 1927(d)(5), and the Eleventh Circuit relied heavily on the First Circuit's decision in *Concannon*. If the Court ultimately reverses the First Circuit's decision, at the very least it would be appropriate to grant the petition, vacate the Eleventh Circuit's decision, and remand for reconsideration

in light of *Concannon*. Accordingly, even if the Court is not inclined to grant full review in this case, it should defer action on the petition pending its decision in *Concannon*.

CONCLUSION

Amici curiae respectfully request that the Court grant the petition for a writ of certiorari. Alternatively, *amici* request that the petition be held pending this Court's disposition of *Concannon*.

Respectfully submitted,

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